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10/549,961	09/16/2005	Gerard M Nolan	03-40062-US	8365

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EXAMINER	
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ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,961	NOLAN, GERARD M	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/2007, 3/29/2007, 11/4/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II and the election of Stargardt disease in the reply filed on October 30, 2008 is acknowledged. The traversal is on the grounds that the WIP PCT ANNEX B, Part 2 found unity of invention and that there is no search burden for examination. This is not found persuasive because the claims at the time of restriction did not have a technical feature linking the groups as Group II did not require an acetylcholinesterase inhibitor as cited in the other Groups. Additionally, the current technical feature for the groups is an acetylcholinesterase inhibitor composition which can be found in Hussain (U.S. Pat. 3681495). Thereby there is no special technical feature. The argument in regards to burden is not found persuasive because the instant case is submitted under 35 U.S.C. 371, the Unity of Invention practice in MPEP §1850 and MPEP §1893.03(d) was followed, not restriction practice. Thus the criteria for burden stated in MPEP §803 for national applications filed under 35 U.S.C. 111(a) does not apply (MPEP §801). The lack of unity has been addressed in the previous action. As the technical feature did not contribute over the art, the restriction was applied appropriately.

The requirement is still deemed proper and is therefore made FINAL.

Status of Application

2. Applicant has elected Group II in response to restriction requirement and elected the species Stargardt disease for the examination.

Due to restriction, based on election of Group II, claims 1-6 and 17-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 7-16 are present for examination at this time.

Claim Objections

3. Claim 7-16 are objected to because of the following informalities: The claims draw to "acetylcholine esterase inhibitor" which is misspelled. The correct term is "acetylcholinesterase inhibitor". Appropriate correction is required.

Information Disclosure Statement

4. The information disclosure statement filed 3/29/2007 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no translation for the Kellner or Laval Medical reference. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

5. The information disclosure statement filed 3/29/2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other

information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The instant claims are directed to an "acetylcholine esterase inhibitor". As a result, the claims cover all compounds having these characteristics or properties, whereas the application provides support for only the compounds (2-mercaptoethyl)trimethylammonium iodide O,O-diethyl phosphorothioate (also known as either echothiophate iodide or PHOSPHOLINE IODIDE) and physostigmine within the scope of what is claimed. There is no evidence that there is any per se structure/function relationship between the disclosed compounds and any others that might be found in the future. It is noted that there are still screening processes currently for acteylcholinesterase inhibitors (see Gallagher U.S. Pat. Pub. 2005/0267077, paragraph 42) as not all of the inhibitor are known. There are no structural identifying characteristics for the group of "acetylcholine esterase inhibitor" compounds are not disclosed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus such as a disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, the amount of binding desired for the receptors, structure/function correlation or any combination thereof, and the compounds that would accomplish this other than (2-mercaptoethyl)trimethylammonium iodide O,O-diethyl phosphorothioate which is disclosed in the specification, but as a single species, does not provide sufficient descriptive support for the myriad of compounds embraced by the claims. Therefore, the claimed invention for the genus is not supported by adequate written description and only that compound is to be considered.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 7-10, 12, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nolan (U.S. Pat 6273092).

Nolan teaches a method of restoring vision to patient by topically administering a (2-mercaptoethyl)trimethylammonium iodide O,O-diethyl phosphorothioate (also known as either echothiophate iodide or PHOSPHOLINE IODIDE) composition before sleeping for several disorders related to reading vision. These include myopia, glaucoma, and

cataracts. The composition comprises preferred concentration of echothiophate iodide including 0.03% and 0.0075%, with a general preferred range of about 0.15 to about 0.005%. The composition was administered to patient with presbyopia and the concentrations included 0.0075% topically applied prior to sleeping. The method would inherently treat any patient in the population that had the Stargardt disease which also is known to affect reading vision.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

10. Claims 7-10, 12, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nolan (U.S. Pat. Pub. 2002/0103167).

Nolan teaches a method of treating diminished visual acuity to a patient with a disorder of the posterior region of the eye by topically administering a (2-mercaptoethyl)trimethylammonium iodide O,O-diethyl phosphorothioate (also known as either echothiophate iodide or PHOSPHOLINE IODIDE) composition before sleeping for several disorders including diabetic retinopathy, branch retinal vein occlusion, AMD, and Leber's Congenital Amaurosis. The composition comprises preferred concentration echothiophate iodide including about 0.03% and about 0.0075%, with a general range of about 0.15 to about 0.005%. The composition was administered to patient with dry AMD, wet AMD, macular hole, solar retinopathy, Leber's Congenital Amaurosis, and retinal diseases such as diabetic retinopathy with macularpathy, and retinal vascular occlusion and the concentrations included 0.03% topically applied prior to sleeping. The

method would inherently treat any patient in the population that had the Stargardt disease which is also a retinal condition of the eye (posterior).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 11, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nolan (U.S. Pat 6273092) or Nolan (U.S. Pat. Pub. 2002/0103167).

The teachings of both Nolan (U.S. Pat 6273092) and Nolan (U.S. Pat. Pub. 2002/0103167) are addressed above.

Nolan (U.S. Pat 6273092) and Nolan (U.S. Pat. Pub. 2002/0103167) do not expressly cite the specific amount of 0.001%, 0.010%, 0.015%, 0.02% .

Nolan does however teach the general concentration range of 0.001% to about 0.25% for echothiophate iodide.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to optimize the amount of echothiophate iodide within the ranges taught by Nolan and produce the instant invention. It would have been obvious to one skilled in the art at the time of invention to determine all optimum and operable

conditions (e.g. the optimal amount of echothiophate iodide), because such conditions are art-recognized result-effective variables that are routinely determined and optimized in the art through routine experimentation. ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). *See* MPEP § 2145.05).

One of ordinary skill in the art would have been motivated to do this because it is desirable to discover the optimal amount of drug for the desired amount of effectiveness for the conditions treated.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 7-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 45-46, 48-57 of copending Application No. 10389823. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are both methods of treating vision related to Stargardt with the same compound in similar if not identical concentrations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claim 7-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-22 of U.S. Patent No. 6540990. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are more specific than that of the issued patent as Stargardt is known to have color blindness issues and the instant claims anticipate the broader issue claims that is using the same compound and similar if not identical concentrations.

16. Claim 7-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 31 of U.S. Patent No. 6605640. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are more specific than that of the issued patent as Stargardt is a known retinal condition affecting the posterior portion of the eye and the instant claims anticipate the broader issue claims that is using the same compound and similar if not identical concentrations.

17. Claim 7-16 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-30, 32-47 of U.S. Patent No. 6605640 in view of Chow et al. (U.S. Pat Pub. 2003/0014089). The instant claims are obvious over the conflicting claims as Stargardt's disease is a known condition affecting the posterior portion of the eye and other commonly known conditions of the posterior portion of the eye include AMD and diabetic retinopathy which are claimed in the patent as taught by Chow et al. (Paragraph 4).

18. Claim 7-16 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6273092. The instant claims are obvious over the conflicting claims as Stargardt's disease is a known condition affecting reading vision among other areas of visual acuity.

Conclusion

19. Claims 7-16 are rejected.

20. The following pieces of art are cited as relevant but are not relied on for the art rejection: Shah et al., Collee et al..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612